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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,461	12/06/2001	Michael Mitsunaga	998046 PA2	7849

30781 7590 01/28/2003

PHILIP K. YU
20955 PATHFINDER ROAD
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EXAMINER

CAMPBELL, THOR S

ART UNIT	PAPER NUMBER
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3742

DATE MAILED: 01/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/010,461

Applicant(s)

MITSUNAGA ET AL. 6

Examiner

Thor S. Campbell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 29-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> . | 6) <input type="checkbox"/> Other: . |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-28, drawn to system for warming a fluid and a cartridge for use therein, classified in class 392, subclass 470.

II. Claims 29-31, drawn to method of warming fluids in a medical application, classified in class 392, subclass 465.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the method can be performed by a different apparatus such as by running the tubing through a warm water bath in order to warm the fluid.

During a telephone conversation with Phillip Yu on 11/19/02 a provisional election was made without traverse to prosecute the invention of I, claims 1-28. Affirmation of this election must be made by applicant in replying to this Office action. Claims 29-31 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 9-13, 17-20, 22-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Ford et al. (US 5381510).

Ford discloses an apparatus for heating fluids comprising a cassette means for transferring heat to fluids flowing therethrough, the cassette means comprising rigid passageway means for defining a thin, planar, elongated, sinuous flow path having first and second sides and an inlet end and an outlet end, such that a thin sheet of fluid enters the inlet end, travels through the flow path, and exits the outlet end; at least one flexible, heat conductive membrane means supported by the passageway means on at least one of the first or second sides of the flow path, for providing heat transfer to at least one of the top and bottom sides of the flow path; a heating means in contact with at least one of said at least one heat conductive membrane means for generating heat energy, said heating means comprising a heating element means for generating a gradation of heat energy such that more heat energy is available for transfer to the parenteral fluid at the inlet end of the sinuous flow path than is available for transfer to the parenteral fluid at the outlet end of the sinuous flow path, having a shape that is essentially a mirror image of the elongated sinuous flow path, and the heating element means being spaced from and in alignment

with at least one of the first or second sides of the elongated flow path and at least one heat sensor means comprising a thermistor and positioned to sense temperatures in different regions.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ford et al. (US 5381510).

Ford discloses an apparatus for heating fluids comprising a cassette means for transferring heat to fluids flowing therethrough, the cassette means comprising rigid passageway means for defining a thin, planar, elongated, sinuous flow path having first and second sides and an inlet end and an outlet end, such that a thin sheet of fluid enters the inlet end, travels through the flow path, and exits the outlet end; at least one flexible, heat conductive membrane means supported by the passageway means on at least one of the first or second sides of the flow path, for providing heat transfer to at least one of the top and bottom sides of the flow path; a heating means in contact with at least one of said at least one heat conductive membrane means for generating heat energy, said heating means comprising a heating element means for generating a gradation of heat energy such that more heat energy is available for transfer to the parenteral fluid at the inlet end of the sinuous flow path than is available for transfer to the parenteral fluid at the outlet end of the sinuous flow path, having a shape that is essentially a mirror image of the

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elongated sinuous flow path, and the heating element means being spaced from and in alignment with at least one of the first or second sides of the elongated flow path and at least one heat sensor means comprising a thermistor and positioned to sense temperatures in different regions.

Ford does not explicitly disclose a single membrane covering both sides of said rigid passageway. It would have been obvious to one having ordinary skill in the art at the time the invention was made to , since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art.

Howard v. Detroit Stove Works, 150 U.S. 164 (1893).

Claims 6-8, 14-16, and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ford et al. in view of Patel et al. (US 5533992).

Ford discloses an apparatus for heating fluids comprising a cassette means for transferring heat to fluids flowing therethrough, the cassette means comprising rigid passageway means for defining a thin, planar, elongated, sinuous flow path having first and second sides and an inlet end and an outlet end, such that a thin sheet of fluid enters the inlet end, travels through the flow path, and exits the outlet end; at least one flexible, heat conductive membrane means supported by the passageway means on at least one of the first or second sides of the flow path, for providing heat transfer to at least one of the top and bottom sides of the flow path; a heating means in contact with at least one of said at least one heat conductive membrane means for generating heat energy, said heating means comprising a heating element means for generating a gradation of heat energy such that more heat energy is available for transfer to the parenteral fluid at the inlet end of the sinuous flow path than is available for transfer to the parenteral fluid at the outlet end of the sinuous flow path, having a shape that is essentially a mirror image of the

elongated sinuous flow path, and the heating element means being spaced from and in alignment with at least one of the first or second sides of the elongated flow path and at least one heat sensor means comprising a thermistor and positioned to sense temperatures in different regions. Ford does not explicitly disclose the rigid passageway, and the film or membrane being made of a non-DEHP plastic.

Patel discloses a non-DEHP material for use in medical applications in order to avoid possible carcinogens dissociating from the plastic and entering the fluid. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use non-DEHP plastic for the flow chamber in the device, since it has been held to be within the general skill or a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Cassidy et al. (US 6175688) and Aid (US 4574876) disclose fluid warming devices similar to applicants invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thor S. Campbell whose telephone number is 703-306-9042. The examiner can normally be reached on Tue-Fri 5:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Teresa Walberg can be reached on 703-308-1327. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0861.

TSC
January 24, 2003



THOR CAMPBELL
PATENT EXAMINER